

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESAL PRICE
LITIGATION

)
)
) MDL NO. 1456
) Civil Action No. 01-12257-PBS
)

THIS DOCUMENT RELATES TO:

) Judge Patti B. Saris
)

The City of New York v. Abbott Labs., et al.

(S.D.N.Y. No. 04-CV-06054)

County of Suffolk v. Abbott Labs., et al.

(E.D.N.Y. No. CV-03-229)

County of Westchester v. Abbott Labs., et al.

(S.D.N.Y. No. 03-CV-6178)

County of Rockland v. Abbott Labs., et al.

(S.D.N.Y. No. 03-CV-7055)

County of Dutchess v. Abbott Labs, et al.

(S.D.N.Y. No. 05-CV-06458)

County of Putnam v. Abbott Labs, et al.

(S.D.N.Y. No. 05-CV-04740)

County of Washington v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00408)

County of Rensselaer v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00422)

County of Albany v. Abbott Labs, et al

(N.D.N.Y. No. 05-CV-00425)

County of Warren v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00468)

County of Greene v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00474)

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**DEFENDANTS'¹ JOINT REPLY MEMORANDUM OF LAW IN
SUPPORT OF MOTION TO DISMISS (1) THE CONSOLIDATED
COMPLAINT OF THE CITY OF NEW YORK AND PLAINTIFF NEW
YORK COUNTIES OTHER THAN NASSAU AND (2) THE
SECOND AMENDED COMPLAINT OF NASSAU COUNTY**

¹ Each defendant has joined in this Motion only as to those cases in which the defendant is a party. Defendants included herein reserve all rights to move to dismiss the Consolidated Complaint and the Nassau County Second Amended Complaint on the basis of improper jurisdiction.

County of Saratoga v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00478))
County of Columbia v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00867))
Essex County v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00878))
County of Chenango v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00354))
County of Broome v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00456))
County of Onondaga v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00088))
County of Tompkins v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00397))
County of Cayuga v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00423))
County of Madison v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00714))
County of Cortland v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00881))
County of Herkimer v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00415))
County of Oneida v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00489))
County of Fulton v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00519))
County of St. Lawrence v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00479))
County of Jefferson v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00715))
County of Lewis v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00839))
County of Chautauqua v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06204))
County of Allegany v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06231))
County of Cattaraugus v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06242))
County of Genesee v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06206))
County of Wayne v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06138))
County of Monroe v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06148))
County of Yates v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06172))

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County of Niagara v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06296))
County of Seneca v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06370))
County of Orleans v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06371))
County of Ontario v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06373))
County of Schuyler v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06387))
County of Steuben v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06223))
County of Chemung v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06744))
AND)
County of Nassau v. Abbott Labs, et al.)
(E.D.N.Y. No. 04-CV-5126))
_____)

Preliminary Statement

The plaintiff New York counties and the City of New York (collectively, the “Counties”) purport to recognize the applicability of law-of-the-case and *stare decisis* to this motion to dismiss based on this Court’s decisions in *County of Suffolk* and *Commonwealth of Massachusetts*.² However, plaintiffs spend most of their consolidated opposition to defendants’ motion (hereafter “C.C. Opp. Br.”) rearguing or mischaracterizing those decisions.

For example, plaintiffs devote the last third of their brief, C.C. Opp. Br. at 26-39, to rearguing the breach of contract/third-party beneficiary, common law fraud and RICO counts that the Court dismissed in *Suffolk I*. The Counties also misrepresent that this Court “sustained” Suffolk’s standing to assert claims for unjust enrichment and for violations of N.Y. Soc. Sec. Law § 145-b and N.Y. Gen. Bus. Law § 349. *See* C.C. Opp. Br. at 7. In fact, the Court (1) held that Section 145-b did *not* permit Suffolk’s claim that manufacturers made “lower payments to the State” than those required by the Medicaid rebate statute; (2) “decline[d] to dismiss” the GBL § 349(b) claims pending a New York Court of Appeals decision on point; and (3) “le[ft] aside the thorny issue” of whether Suffolk could claim unjust enrichment to pursue their “AWP fraud” claims. *Suffolk I*, 339 F.Supp.2d at 180, 181-183.

The only claims that were “sustained” in *Suffolk I*, *i.e.*, those not dismissed outright or deferred for later decision, were the Section 145-b claim as to the alleged “AWP fraud” and the unjust enrichment claim for alleged underpayment of Medicaid rebates. Those latter claims were subsequently dismissed as to almost all defendants in *Suffolk II* and the

² *County of Suffolk v. Abbott Labs.*, 339 F. Supp. 2d 165 (D. Mass. Sep. 30, 2004) (*Suffolk I*); *County of Suffolk v. Abbott Labs*, 2004 WL 2387125 (D. Mass. Oct. 26, 2004) (*Suffolk II*); November 23, 2004 Clarification Order (the Clarification Order); April 8, 2005 *Memorandum and Order* (*Suffolk III*); and *Massachusetts v. Mylan Labs*, 357 F. Supp. 2d 314 (D. Mass. 2005) (the *Massachusetts Action*). References to individual case names in which the City of New York or a New York county is a plaintiff are in italics (*e.g.*, “*Suffolk*”). References to the plaintiff city or county itself in those cases are by name of the city or county without italics (*e.g.*, “Suffolk”). Other abbreviations or defined terms have the same meaning as those in Defendants’ Joint Memorandum of Law In Support of the Motion to Dismiss filed on March 3, 2006, hereafter referred to as “Def. Jt. Mem.”

Clarification Order under Fed. R. Civ. P. 8(a). Plaintiffs simply cannot have it both ways: they cannot rely upon law-of-the-case and *stare decisis* as to the two causes of action the Court “sustained” and avoid the doctrines as to everything else that was dismissed with prejudice. Accordingly, the Court should again dismiss all counts for common law fraud, contract, and Section 145-b (as to Medicaid rebates), as well as for implied causes of action under the federal Medicaid rebate statute. However, in case the Court is inclined to reconsider the merits of its prior decisions, we briefly respond to plaintiffs’ arguments on these claims (*see* Point I) and take the opportunity to revisit the one Section 145-b claim -- as to alleged AWP fraud -- that the Court did sustain (*See* Point II).

Plaintiffs’ arguments as to the New York Court of Appeals decision on GBL § 349 and the implied state law causes of action *not* previously considered by this Court should also be rejected. *See* Point III. Plaintiffs acknowledge that *Blue Cross & Blue Shield of N.J., Inc. v. Phillip Morris, USA*, 3 N.Y.3d 200, 785 N.Y.S.2d 399 (2004), bars “derivative” claims, but contend that the Counties’ injuries are not derivative of the State’s. The Court can easily dispose of that contention: New York Social Services Law §§367-b(2) and (6) provide that the payments made to Medicaid pharmacies in this case are “enforceable only against the state” and that the Counties are derivatively liable to the State for the amount the Counties “*would have borne . . . had the expenditure been made by*” the Counties. *Id.* (italics added). Moreover, plaintiffs have no valid response to the September 2005 testimony of the Executive Director of their own New York Association of Counties before the New York State Senate, who confirmed New York counties’ lack of standing to sue in cases of this nature. They sheepishly write that the Association of Counties has “no authority to bind plaintiffs,” C.C. Opp. Br. at 23, but there can be no doubt that the testimony describes a legislative and administrative construct for

policing Medicaid fraud and abuse in New York that belies any attempt to imply causes of action in favor of the Counties under the state statutes and regulations pled.³

Finally, plaintiffs *admit* (albeit in a separate brief in response to defendant Amgen) that, for physician-administered drugs, New York law has *not* provided for AWP-based reimbursement since 1994. *See* Plaintiffs' Opposition to Defendant Amgen, Inc.'s Individual Memorandum In Support of Motion to Dismiss at 5. Thus, all of the allegations as to that category of drugs must be stricken, leaving in the cases of some manufacturer-defendants *no* particularized allegations of "AWP fraud" or "WAC fraud" such as was required by this Court in the *Massachusetts Action*.⁴ Indeed, as we demonstrate below, if any of the Counties' causes of action survive law-of-the-case and Fed. R. Civ. P. 12(b)(6), they must nevertheless be dismissed under Fed. R. Civ. P. 8(a) and 9(b). Neither the allegations contained in the text of the Consolidated Complaint and the Nassau SAC nor the tables in the exhibits annexed thereto provide the missing details that this Court required in *Suffolk II* and *III* and in the *Massachusetts Action* to allow a suit challenging thousands of AWPs, WACs and best prices of scores of manufacturers for a time period stretching over a decade. *See* Point IV.

³ Plaintiffs note that, as of December 2005, a handful of counties have applied under a new State "Demonstration Project" statute for authority to bring this suit. *See* C.C. Opp. Br. at 15 n.22; Declaration of Joanne M. Cicala in Opposition to Motion to Dismiss Ex. B. Yet, the statute cited by the Counties on its face allows for projects relating to "delivery of quality health care services," not for litigation projects. *See* N.Y. 2005 Laws, Ch. 58, Part. C, § 5, annexed as Exhibit A. Moreover, there is no indication that the few counties that applied have actually *obtained* authority from the State to bring this suit. Finally, plaintiffs offer no explanation why dozens of the other above-captioned counties and New York City have not even applied for authorization to proceed. In reality, the new law only confirms that Medicaid fraud litigation remains the province of the State. *See id.* at § 6(2)(a) (counties should report suspected provider fraud to "appropriate state authorities.").

⁴ Plaintiffs fail to address the change in their theory of the case from one of "AWP Fraud" to "WAC Fraud." *See* Cons. Comp. ¶¶ 7-8 ("[T]his case is not about the 20-25% mark up between WAC and AWP . . . [t]his case concerns that WAC itself is false and misleading . . ."). Similarly, plaintiffs disregard this Court's ruling in the *Massachusetts Action* that plaintiffs were required "to state, drug-by-drug, the allegedly false representations" on which plaintiffs claim to have relied. *See Massachusetts v. Mylan*, Civ. No. 03-11865, slip op. at 2 (D. Mass. April 5, 2005)..

Argument

POINT I

THE COURT SHOULD ADHERE TO ITS PRIOR RULINGS
DISMISSING PLAINTIFFS' CONTRACT, FRAUD AND RICO CLAIMS

Plaintiffs claim they do not seek to reargue the dismissal of their proposed implied causes of action under the federal rebate statute. Rather, they say that they merely wish to preserve those causes of action for appeal, *see* C.C. Opp. Br. at 4 n. 10 (*citing Suffolk I*); however, they seem to think that the Court is interested in hearing reargument of their breach of contract, common law fraud and RICO counts. For the reasons below, the Court should adhere to its prior rulings.

A. Breach of Contract

Plaintiffs make two arguments in support of their request for reconsideration of the Court's dismissal of Suffolk's breach of contract/third-party beneficiary claims. First, they argue that they are "suing on behalf of the State" as agents. C.C. Opp. Br. at 27 & n. 32. Second, they claim that the Court should consider the "peculiarity of relations among the parties . . . [outside] the four corners of the [Medicaid rebate] contract." *Id.* at 28. Neither argument has any merit.

First, if plaintiffs were really agents of New York State for Medicaid rebate purposes, they would not need to proceed on a third-party beneficiary theory: they could sue directly for breach of contract in the name of the State as agent. The fact that the Counties pled the cause of action as third-party beneficiaries establishes that they know themselves not to be

the State's agents. Indeed, the one case that plaintiffs cite, *Beaudoin v. Toia*, 45 N.Y.2d 343 (1978) – to the extent that it is relevant at all – confirms this.⁵

Plaintiffs cite *Org'n of Minority Vendors v. Illinois Central Gulf R.R.*, 579 F. Supp. 574 (N.D. Ill. 1983) for the proposition that the Court should look beyond the relevant contract to determine whether a plaintiff is a third-party beneficiary. Plaintiffs badly misread this case. In *Org'n of Minority Vendors*, the court granted third-party beneficiary status to plaintiffs because “[o]ur analysis above of the funding agreements . . . and the statutory, regulatory and operational context of these contracts indicate that they were made for the direct benefit of a limited class, the MBEs [plaintiff minority business enterprises].” *Id.* at 600. Thus, an evaluation of the contract language and the direct benefit to plaintiff were integral parts of the result. In short, the case cited by plaintiffs employed the same analysis that this Court employed in *Suffolk I* and would produce the same dismissal of plaintiffs’ third-party beneficiary theory here. See *InterGen, N.V. v. Grina*, 344 F.3d 134, 147 (1st Cir. 2003) (third-party beneficiary status requires contractual intent to “confer specific legal rights” on would-be plaintiff).

B. Fraud

Plaintiffs argue that the Court’s reference in *Suffolk I* to “terse” briefing applies to the fraud claim and that this “unfortunate [briefing] no doubt contributed to this Court’s clearly erroneous decision.” C.C. Opp. Br. at 29. Plaintiffs then launch into six pages of discussion of how New York law supposedly permits a plaintiff who was never exposed to an alleged

⁵ *Beaudoin* involved Aid to Families with Dependent Children (welfare), not Medicaid. The statute implementing that program provided that county commissioners of social services, not the counties themselves, are agents or “local arm[s]” of the State. *Id.* at 346. In addition, the *Beaudoin* court held that the county commissioners, as agents, are bound to act in accordance with the directives of the State Department of Social Services even if those directives are inimical to the counties’ own financial interests. It specifically held that the counties have no standing to challenge the State’s “fair hearing” determination on behalf of a welfare recipient. *Id.* The holding accordingly supports defendants’ argument here that if any entity has standing to sue, it is the State rather than the Counties.

misrepresentation to nevertheless satisfy the reliance requirement by pointing to a third-party who was. C.C. Opp. Br. at 29-34.

This argument is disingenuous. First, the Court's reference to "terse" briefing was clearly a reference to the briefing on the state law causes of action *besides* fraud. *See* 339 F.Supp.2d at 183 (referring to the alleged implied claims under New York statutes and regulations). The fraud claim had been examined much earlier in the opinion and the briefing leading up to the decision had been full and fair.

More importantly, plaintiffs relegate to a footnote the fact that this Court reviewed the precise line of cases to which they now devote six pages. *See* C.C. Opp. Br. at 31 n.34. Specifically, this Court cited the Second Circuit's decision in *Cement & Concrete Workers Dist. Council Welfare Fund, Pension Fund, Legal Serv. Fund & Annuity Fund v. Lollo*, 148 F.3d 194, 196 (2d Cir. 1998) for the proposition that third-party reliance was insufficient, and then the Court added:

But see N.B. Garments (Pvt.) Ltd. v. Kids Int'l Corp., No. 03-8041, 2004 WL 444555, **3-4, 2004 U.S. Dist. LEXIS 3774, at *9-12 (S.D.N.Y. March 10, 2004) ("Further, the fact that the First and Second Departments have, subsequent to the Second Circuit's decision in *Cement & Concrete Workers* altered their stance, and held in accord with the *Eaton* line – even citing to the century old Court of Appeals decisions, lends further support for the determination that New York law has, since the 1800's, allowed for fraud claims based on third-party reliance.").

339 F.Supp.2d at 180-81. This Court thus plainly considered *N.B. Garments* and related cases in making its previous ruling.⁶

Finally, even if this Court were to decide to revisit the reliance issue, the case law would lead to the same conclusion reached in *Suffolk I*. The cases allowing

⁶ Courts continue to reject New York common law fraud claims where plaintiffs can only demonstrate reliance by a third party on the alleged misrepresentations. *See e.g., Federal Treasury Enter. Sojuzplodoimport v. Spirits Int'l N.V.*, 2006 WL 851724 (S.D.N.Y. Mar. 31, 2006) ("A claim for fraud cannot lie under New York law where the alleged misrepresentation is made to and relied upon by a third party, but not the plaintiff.").

third-party reliance are special ones in which the plaintiff and the defendant are in privity, but the defendant's representation is made to an intermediary upon whom plaintiff relied. *See, e.g., Union Carbide Corp. v. Montell N.V.*, 9 F.Supp.2d 405, 411-12 (S.D.N.Y. 1998) (buyer of business sued seller over misrepresentations made to independent appraiser upon whom parties relied for price information); *Hyosung America, Inc. v. Sumagh Textile Co., Ltd.*, 25 F.Supp.2d 376 (S.D.N.Y. 1998) (defendant misrepresented the quality of its textile product to issuer of letter of credit in favor of plaintiff); *Desser v. Schatz*, 182 A.D.2d 478, 479-80, 581 N.Y.S.2d 796, 796-97 (1st Dep't 1992) (defendants' misrepresentation to plaintiff's bank that defendants had paid underlying loan on mortgaged property fraudulently extinguished plaintiff's rights as mortgagor); *Caramante v. Bartoni*, 114 A.D.2d 680, 682, 494 N.Y.S.2d 498, 500 (3d Dep't 1985) (defendant property owner misrepresented habitability of property to plaintiff's bank upon which plaintiff relied in closing on sale); *Tindle v. Birkett*, 171 N.Y. 520, 522-23 (1902) (defendant misrepresented his business' solvency to credit rating agency to induce plaintiff, who relied upon credit rating agency's report, to extend lines of credit to defendant); *The Eaton, Cole & Burham Co. v. Avery*, 83 N.Y. 31 (1880) (same).⁷

Here, by contrast, there is no relationship between the drug manufacturers and the Counties, nor do the Counties rely on anything the manufacturers represent to the State. As the Court pointed out in *Suffolk I*, "the State set the [Medicaid] reimbursement procedures with no input from Suffolk." 339 F.Supp.2d at 180. Thus, while the Counties are claiming indirect loss

⁷ Inexplicably, plaintiffs cite to *Semi-Tech Litig. v. Ting* and *John Blair Commc'ns, Inc. v. Reliance Capital Group, L.P.*, for the proposition that New York recognizes third party reliance in a fraud action. C.C. Opp. Br. at 32 n. 34. Those cases, however, do not involve third party reliance. They involve whether an accountant has a duty to someone not his client. In both cases, the defendant accountant made misrepresentations *directly to the plaintiff*. The disputed issue was whether plaintiff – who was not the accountant's client – had standing to sue for the misrepresentations. *Semi-Tech Litig. v. Ting*, 13 A.D.3d 185, 188, 787 N.Y.S.2d 234, 237 (1st Dep't 2004); *John Blair Commc'ns v. Reliance Capital Group, L.P.* 137 A.D.2d 490, 490-91, 549 N.Y.S. 678, 679-80 (1st Dep't 1990).

causation through defendants' alleged misrepresentations to the State about drug prices (*but see* discussion of GBL § 349, *infra*), they cannot even allege indirect *transaction* causation (*i.e.*, reliance) on the State because the Counties have no say in determining how much Medicaid pays pharmacies for drugs. In sum, the Court properly analyzed New York law of third-party reliance in fraud cases in *Suffolk I* and correctly dismissed that cause of action.⁸

C. RICO

Nassau County notes that the Court dismissed Suffolk's RICO "Publisher Enterprise" claim without prejudice, C.C. Opp. Br. at 35, but it does not distinguish its pleading from Suffolk's, nor does it explain how its alleged Publisher Enterprises are materially different from those that were dismissed *with* prejudice in this Court's very first decision in this MDL: *In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F.Supp.2d 172, 184-85 (D. Mass. 2003) ("*Pharm I*").

In *Pharm I*, the Court analyzed three types of "hub and spoke" enterprises alleged between each manufacturer defendant and (1) medical providers; (2) PBMs; and (3) industry publications. It noted that "[m]ost courts have found that complaints alleging hub-and-spoke enterprises fail to satisfy the RICO enterprise requirement," *id.* at 183, and held that the alleged participants' mutual interest in making money did not give rise to a "common purpose" that would qualify as an association-in-fact. *Id.* at 183-84. The Court went on to hold that the "Publisher Enterprises" present an even weaker theory" than the other two enterprises pled

⁸ As one federal court explained in rationalizing the various New York cases, the only exception to the otherwise "absolute rule" that third party reliance cannot support a claim of fraud lies where there is (1) a direct relationship within the alleged fraudulent transaction between plaintiff and defendant; (2) the representation to a third party was made known to plaintiff; and (3) defendant intended plaintiff to rely on the statement even though it was transmitted to a third party. *Horizon Cruises Litig.*, 1999 WL 436560, *1-2 (S.D.N.Y. 1999); *See also Barnhart v. Federated Dep't Stores, Inc.* 2005 WL 549712 (S.D.N.Y. 2005) (citing *SIPC v. BDO Seidman, LLP*, 222 F.3d 63, 71-71 (2d Cir. 2000) (plaintiffs alleging third party reliance when pleading New York common law fraud must demonstrate that they relied upon the representation to the third party and that defendants intended such reliance). This "exception" is not applicable here.

because “[t]here is no allegation that the publishing companies even benefited from the ‘spread’ scheme other than by the profits generated for publishing data provided to them.” *Id.* at 184.

Nothing in the Nassau SAC corrects this fundamental omission. Indeed, the Nassau SAC reiterates that the Publishers received nothing more from their participation in the alleged enterprise than “protect[ing] the supply” of data they received from the manufacturers for publication. Nassau SAC at ¶ 735. Further, just as in *Suffolk I*, there are “no details [in the Nassau SAC] about the interaction between the publishers and the manufacturers sufficient to meet Fed. R. Civ. P. 9(b).” Therefore, if Nassau’s RICO claim is not dismissed with prejudice under Rule 12(b)(6) and law-of-the-case based on *Pharm I*, it should now be dismissed with prejudice under Fed. R. Civ. P. 9(b) for *repeated* inability to plead facts supporting a Manufacturer-Publisher RICO enterprise with the requisite particularity. *See Hayduk v. Lanna*, 775 F.2d 441, 445 (1st Cir. 1985) (dismissal with prejudice on Rule 9(b) grounds “well within the discretion of the district court” after plaintiff had opportunity to amend complaint).

POINT II

IF THE COURT RECONSIDERS ITS PRIOR RULINGS IT SHOULD DISMISS PLAINTIFFS’ AWP/WAC FRAUD CLAIM UNDER N.Y. SSL § 145-b

Unlike plaintiffs, defendants *are* willing to accept the logical consequences of law-of-the-case and *stare decisis* – that is, to take the “bad” with the “good” (depending on a party’s perspective) of this Court’s prior decisions upholding some of the Counties’ causes of action and dismissing most others. However, if the Court is inclined to accept plaintiffs’ invitation to revisit any of the claims that it previously dismissed, defendants request that the Court also reconsider its decision upholding plaintiffs’ N.Y. Soc. Sec. Law § 145-b claims as to an alleged AWP/WAC fraud.

Defendants' argument is simple: while Section 145-b grants a county standing to sue, the only proper defendants are those who have "obtain[ed] payment from public funds" either themselves or as agents for Medicaid providers. This Court previously ruled that the language "on behalf of himself or others" modifies the phrase "knowingly by means of a false statement . . ." so as to permit suit against one who does not receive Medicaid funds, but whose false statement was a cause-in-fact of another's receipt of such funds. *Suffolk I*, 339 F.Supp.2d at 179.

As we have shown, such a broad reading of the statute is inconsistent with its legislative history. *See* Def. Jt. Mem. at 23-24. The phrase "on behalf of ...others" should be read to modify the phrase "obtain payment" so as to allow suits against intermediaries (*e.g.*, billers) or affiliates (*e.g.*, professional corporations) who obtain funds *on behalf of* Medicaid providers. Plaintiffs make no argument in response, saying that the statute itself is clear and the Court should not resort to the legislative history. C.C. Opp. Br. at 10-12. Defendants believe that the statutory language actually supports their reading⁹ and respectfully suggest that there is at least sufficient ambiguity in the language for this Court to revisit its prior ruling in light of the legislative history, as well as the only other decided case on the issue, *New York v. Pharmacia Corp.*, Index Nos. 905-04, 905-03, 1150-03, slip. op. (N.Y. Sup. Ct. June 1, 2004), which supports defendants' interpretation.

⁹ The construction adopted by this Court requires one to imply the word "made" (or some similar verb) so that the statute would state that "It shall be unlawful for any person knowingly by means of a false statement . . . [made] on behalf of himself or others . . . to attempt to obtain or to obtain payment from public funds . . ." Principles of statutory construction teach that if a word has to be added for the statute to be read in a certain way, then that reading is not favored. *See Lamie v. United States Trustee*, 540 U.S. 526, 534-35, 124 S.Ct. 1023, 1031 (2004) (holding that courts should not "add" missing words when interpreting a statute where the statute's meaning is different but nonetheless ascertainable without the arguably "missing" word). By contrast, defendants' interpretation of the statute does not require any change or addition to the express language of the statute.

POINT III

PLAINTIFFS' GBL § 349, IMPLIED STATE LAW AND UNJUST ENRICHMENT
CLAIMS SHOULD BE DISMISSEDA. GBL § 349

The parties agree that the New York Court of Appeals' decision in *Blue Cross & Blue Shield of N.J., Inc. v. Phillip Morris, USA* bars a plaintiff who suffers "derivative" or "indirect" injury from proceeding under N.Y. General Business Law § 349.¹⁰ 3 N.Y.3d 200, 785 N.Y.S.2d 399 (2004). The only issue for decision, therefore, is whether the Counties' claims in this case are direct or derivative. Plaintiffs argue that the Counties' injuries are direct because "it is not the State but the local districts that bear ultimate financial responsibility for medical assistance to the needy, even if those costs are not reimbursed by the State." C.C. Opp. Br. at 13 (*citing Jones v. Berman*, 37 N.Y.2d 42, 54-55 (1975)). This is just plain false.

In 1976, the New York State legislature changed the Medicaid program so that the claim of a Medicaid provider such as a pharmacist entitled to reimbursement for a drug, "shall be enforceable only by such provider against the state and shall not be enforceable against the social services district." N.Y. Soc. Serv. Law § 367-b(2). While plaintiffs may be correct that the pre-1976 Medicaid statutes still on the books today read "as if" the counties were responsible for paying Medicaid providers, C.C. Opp. Br. at 14 n.20, there is a clear reason why that is so: the 1976 law requires a county to reimburse the state in an amount the county "would have borne [under the pre-1976 laws] *had* the expenditure been made by the county." *Id.* at § 367-b(3) (emphasis added).¹¹

¹⁰ In a footnote plaintiffs cite one lower court opinion, *Cox v. Microsoft*, 8 A.D.3d 39, 40 (1st Dep't 2004), for the proposition that indirect purchasers have standing under the statute. Plaintiffs omit to point out that the case was decided before the Court of Appeals decision in *Blue Cross Blue Shield of N.J., Inc.*

¹¹ Plaintiffs' citation to *Beaudoin v. Toia*, 45 N.Y.2d 343 (1978) included in their standing argument under GBL § 349 provides no arguments to the contrary. See n.5, *supra*.

In short, the relationship between the Medicaid providers and New York state and the relationship between the state and the counties are separate and legally distinct. The only link is that the amount that the county is obligated to reimburse the state was defined to match the amount the county “would have” paid pre-1976 when the relationship between the county and the Medicaid provider was direct.¹² The link is insufficient under *Blue Cross & Blue Shield of N.J., Inc.* and, accordingly, the Counties’ GBL § 349(b) claims should be dismissed.

B. Implied State Law Causes of Action

Plaintiffs claim that “[t]he Court has already sustained County standing” to bring implied rights of action under New York state law. C.C. Opp. Br. at 23 (*citing Suffolk II* at *3). In fact, *Suffolk II* did not touch upon these alleged causes of action in any way. In *Suffolk I*, the Court expressly declined to rule because the briefing on these causes of action was “terse” and resolution of the motion to dismiss would not “affect the scope of the litigation.” 339 F.Supp. at 182. Now the briefing has been full and, since the GBL § 349(b) claim is also ripe for resolution, there is indeed potential to affect the course of this litigation materially through a decision dismissing the alleged implied causes of action under Soc. Sec. Law §§ 366-b, 367-(a)(7)(d) and 18 NYCRR § 515.2(b)(4) & (5).

Plaintiffs variously respond that (1) as counties, they are not implying “private” rights of action for damages, but are suing in governmental capacities for declaratory relief; (2) the Court should ignore the testimony of the Executive Director of the New York Association of Counties which explains why implying rights of action here would contradict the New York Legislature’s balance between State and County Medicaid enforcement; and (3) the fact that

¹² Even this law has changed. In 2005, the New York Legislature “capped” the amount of reimbursement that counties must make to the State. N.Y. 2005 Laws, Ch. 58, Part. C § 1(b). The law further provides for a phasing out of a county’s reimbursement to the State altogether by 2008. *Id.* § 2. The Legislature’s ability to change the funding relationship between the counties and the State further demonstrates how that relationship is legally distinct from the relationship at issue in this AWP litigation – that between the State and the Medicaid providers.

Section 145-b expressly allows for counties to sue should permit this Court to imply remedies under other state laws. C.C. Opp. Br. at 23-26. These arguments are without merit.

First, it does not matter whether the counties are suing “privately” or as government entities; the fact of the matter is that the statutes and regulations they have included in their pleadings do not authorize them (or in the case of SSL § 367-a(7)(d), anyone) to bring any kind of proceeding. A plaintiff cannot simply seek declaratory judgment that a law has been broken; there must be an underlying case or controversy. *See Lake Carriers’ Ass’n v. MacMullen*, 406 U.S. 498, 506, 92 S.Ct. 1749, 1755 (1972); *Gun Owners Action League, Inc. v. Swift*, 284 F. 3d 198, 205-09 (1st Cir. 2002). Thus, the Counties must meet the tests for implying causes of action under *Sheehy v. Big Flats Cmty. Day, Inc.* 73 N.Y.2d 629, 541 N.E.2d 18, 543 N.Y.S.2d 18 (1989) – and they do not.

Second, while the Counties admit that one of the key *Sheehy* factors for implying rights of action is whether doing so is consistent with legislative intent in enacting the statute in question, *see* C.C. Opp. Br. at 26, they have no real response to their Association’s acknowledgement before the New York State Senate that the legislature has “understandably limited” the counties’ roles to policing Medicaid “recipient” fraud, not the “provider” fraud alleged here. They argue that the Association’s testimony is not “binding” or that it related only to the county’s inability to bring “administrative and criminal actions,” not civil actions. C.C. Opp. Br. at 23. Unfortunately, plaintiffs omit to state that several of the statutes under which they seek to imply civil claims are in fact criminal statutes and administrative regulations. In any event, not only do the statutes and regulations themselves clearly show (by referring only to

State entities) that it would be contrary to legislative intent to imply civil causes of action in favor of counties, the testimony at issue applies to civil actions as well.¹³

Third, plaintiffs provide no support for the proposition that because one statute (Section 145-b) expressly provides for a cause of action, other causes of action should be implied under other statutes or regulations. Indeed, because Section 145-b was passed in 1975 -- one year *before* the State assumed from the Counties all responsibility for dealing with Medicaid providers -- it is hardly a reliable indicator of legislative intent under the current structure of New York Medicaid. Further, as recently as last year, the New York State Legislature reaffirmed that the counties' role in policing Medicaid fraud and abuse is limited to a "monitoring" function and to reporting suspected activity to "the [state] commissioner of health . . . the attorney general and other appropriate state authorities." N.Y. 2005 Laws, Ch. 58, Part. C, § 6(2)(a) (annexed hereto as Exhibit A).¹⁴

Finally, the one case plaintiffs cite for the proposition that counties have brought actions similar to this one in the past, *City of New York v. Tobacco Inst., Inc.*, 1997 U.S. Dist. LEXIS 19415 (S.D.N.Y. 1997), C.C. Opp. Br. at 24, is completely inapposite. The court there ruled that the City of New York's lawsuit against tobacco companies did not present

¹³ The testimony concludes that "The local [county] role in Medicaid fraud and abuse control has been understandably limited by the State Health Department, as they [sic] must be assured that there is no duplication of effort, the proper audit procedures are followed, and that there is a consistent application of program requirements pursuant to federal and state regulations." Def. Jt. Mem. Ex. A at 6. This rationale applies equally to civil actions.

¹⁴ Plaintiffs also argue that the State has "endorsed this action" and stated that the "local districts are acting in its interests." C.C. Opp. Br. at 26. By this, presumably plaintiffs mean to refer to the "To Whom It May Concern" letter annexed as Exhibit C to plaintiffs' counsel's declaration in which a deputy commissioner of the State Office of Medicaid Management acknowledges the prosecution of this lawsuit by the Counties. The letter states that counsel, in prosecuting the litigation, is "deputize[d] . . . as representing the State of New York's interests for the purposes of the described litigation." It is far from clear what this official means by New York's "interests," but it is irrelevant to the only pertinent issue of whether the legislature intended to create remedies for the counties. Furthermore, Plaintiffs' argument that they are acting in the State's interests is belied by the fact that the New York Attorney General has brought suit against three of the same manufacturers for the same alleged conduct that Plaintiffs seek recovery for in this case. See *People of the State of New York v. Pharmacia*, Civ. Action No. 05-12496-PBS, *People of the State of New York v. Aventis Pharmaceuticals, Inc.*, Civ. Action No. 05-12497-PBS, and *People of the State of New York v. GlaxoSmithKline, P.L.C. et al.*, Civ. Action No. 05-12498-PBS remanded to state court in *In re Pharma, Indus. Average Wholesale Price Litig.*, March 13, 2006 Memorandum and Order.

a substantial federal question. It had nothing to do with the City's authority to bring suit under Medicaid, let alone whether it had implied rights of action under the particular New York state statutes or regulations at issue here.

C. Unjust Enrichment

In *Suffolk I*, this Court left “aside the thorny issue of whether Suffolk may recover [on a theory of unjust enrichment] from Defendants to the extent that the AWP fraud boosted their sales. . . .” 339 F.Supp.2d at 181. Turning to the best price claim – that “Defendants were ‘saved from expense’ when they fraudulently underpaid Best Prices rebates” – the Court noted that plaintiffs’ allegations did suffice to state a cause of action for unjust enrichment. *Id.* The Court added, however, that it was not opining on a county’s standing to bring such a claim. *Id.* at 181 n.6 (“While Defendants make reference to the issue of whether Suffolk has standing . . . Defendants fail to argue the issue with specificity to a particular cause of action”).

In *Suffolk II* and the Clarification Order, the Court subsequently dismissed Suffolk’s best price/unjust enrichment claims as to virtually all defendants under Rule 8(a). As discussed in Point IV.A, *infra*, the Consolidated Complaint and Nassau SAC do not address the Court’s concerns expressed in those decisions. Thus, the best price/unjust enrichment claims should again be dismissed for pleading defects – this time with prejudice. They should also be dismissed under Fed. R. Civ. P. 12(b)(6) for lack of standing.

First, the very existence of the Medicaid rebate agreements preclude these claims. As defendants explained in their opening brief, unjust enrichment will not lie when a contract covers the subject matter in dispute. Def. Jt. Mem at 24 n.17; *see also Goldman v. Metropolitan Life Ins. Co.*, 5 N.Y.3d 561, 572, 841 N.E.2d 742, 746-47, 807 N.Y.S.2d 583, 587-88 (2005). Plaintiffs accuse defendants of wanting to have it “both ways” arguing that the Counties are not third-party beneficiaries of the rebate agreements yet insisting that they cannot maintain an

unjust enrichment action. C.C. Opp. Br. at 18. There is no inconsistency at all. The existence of the rebate contract bars anyone -- even someone not a party to the contract -- from using an unjust enrichment theory instead of a contract-based claim. *See Granite Partners, L.P. v. Bear Stearns & Co.*, 17 F.Supp.2d 275, 311 (S.D.N.Y. 1998) (existence of contract bars unjust enrichment claim over same subject matter “regardless of whether the contract is one between parties to the lawsuit, or where one party to the lawsuit is not a party to the contract.”).¹⁵

Second, as to the AWP/WAC fraud claims: (1) plaintiffs are unable to overcome the “thorny issue” of relating their payments to the State to defendants’ alleged enrichment through “boosted . . . sales” *Suffolk I* at 181, and (2) plaintiffs lack standing because the Counties do not have the requisite quasi-contractual relationship with drug manufacturers. *See In re Motel 6 Sec. Litig.*, 1997 WL 154011 *7 (S.D.N.Y. 1997) (“[A]n unjust enrichment claim requires some type of direct dealing or actual, substantive relationship with a defendant”).¹⁶ Plaintiffs fail to include in either the Consolidated Complaint or Nassau County SAC any allegation of any

¹⁵ The Counties also argue that they are entitled to plead breach of contract/third-party beneficiary and unjust enrichment in the alternative. C.C. Opp. Br. at 21. As already noted, the Counties are not third-party beneficiaries of the rebate agreements. Moreover, a party can plead unjust enrichment as an alternative to a contract theory only when there is an issue as to whether the contract in question is enforceable or applicable. *See Waxman v. Vipco Pick Up & Processing Servs.*, 2003 WL 22439796 at * 11 (S.D.N.Y., Oct. 28, 2003). Here, there is no question that the Medicaid rebate agreements are both enforceable and applicable – it is just that the Counties are neither parties to nor third party beneficiaries of them.

¹⁶ The absence of a requisite relationship between the Counties and drug manufacturers would also bar the best price/unjust enrichment claims even if there were not a rebate agreement. Plaintiffs respond that New York does not require any relationship between the parties to support an unjust enrichment claim. C.C. Opp. Br. at 17 (citing cases including *Cox v. Microsoft Corp.* 8 A.D.3d 39, 778 N.Y.S.2d 147). As noted above, *Cox* has been effectively overruled on GBL § 349 indirect-purchaser standing by the Court of Appeals decision in *Blue Cross Blue Shield of NJ*. *See discussion, supra* n.10. *Cox* has also been directly called into question for its ruling with respect to standing for unjust enrichment cases. *See Sperry v. Crompton Corp.* 26 A.D.3d 498, 500, 810 N.Y.S.2d 498, 499 (2d Dep’t 2006) (“We decline to follow the decision of the Appellate Division, First Department, in *Cox*, which dispenses with the requirement of privity for a claim sounding in unjust enrichment.”). Plaintiffs’ other cases addressing unjust enrichment standing do not analyze New York law, nor are they applicable here: *See Greenwald v. Chase Manhattan Mortgage Corp.*, 241 F.3d 76, 78. (1st Cir. 2001) (Massachusetts law); *Massachusetts v. Mylan Laboratories*, 357 F.Supp.2d 314, 323-24 (D. Mass. 2005) (Massachusetts law); *In re Cardizem Antitrust Litig.*, 105 F.Supp.2d 618, 669 (E.D. Mich. 2000) (no application of New York unjust enrichment law).

contact with Defendants in any form. Thus, these plaintiffs cannot sue defendants for unjust enrichment.

POINT IV

ANY REMAINING CLAIMS SHOULD BE DISMISSED UNDER F.R.C.P. 9(b) AND 8(a)

A. Best Price/Medicaid Rebate Claims

Even if the Counties had standing to pursue unjust enrichment claims for alleged underpayment of Medicaid rebates, their claims would fail under Rules 9(b) and 8(a) for the same reasons that the Court articulated in *Suffolk II* and the Clarification Order: there are “insufficient facts” pled in the Consolidated Complaint or Nassau SAC to suggest that defendants underpaid rebates or misreported best prices. Plaintiffs state that the Consolidated Complaint “including Exhibits A-D and F, thereto provide all the data the Court required in its prior opinions.” C.C. Opp. Br. at 22 n.29. But all of the allegations and Exhibits cited go to the alleged “AWP/WAC fraud” claims, not to the Medicaid rebate/best price claims. The pleadings are completely devoid of any detail about which rebate on which drug for which time period was incorrect and why. Because plaintiffs have had ample opportunity to replead, all claims as to Medicaid rebates/best price reporting should now be dismissed with prejudice.¹⁷

¹⁷ Plaintiffs correctly note that this Court previously ruled that Fed. R. Civ. P. 9(b) does not apply to unjust enrichment claims. C.C. Opp. Br. at 22 (citing *Suffolk II*). They are incorrect, however, in writing that Defendants have ignored this ruling and offered no basis for its reversal. We cited two cases for the proposition that where, as here, the claim of unjust enrichment is premised on alleged fraudulent misstatements, Rule 9(b) applies. *See* Def. Jt. Mem. at 24 (citing *Daly v. Castro Llanes*, 30 F.Supp.2d 407, 414 (S.D.N.Y. 1998) (Unjust enrichment claim was “subject to Rule 9(b)” because it was premised on fraudulent inducement to deposit money, or was “premiered on fraud”); *Ramapo Land Co. v. Consol. Rail Corp.*, 918 F.Supp. 123, 128 (S.D.N.Y. 1996) (Unjust enrichment claim held subject to the requirements of Rule 9(b) because the “only alleged basis for the claim that the enrichment was unjust lies in the averment of [fraudulent inducement]”)).

B. AWP/WAC Fraud Claims

1. Physician-Administered Drugs

Plaintiffs have conceded that, at least since 1994, New York Medicaid law has provided that physician-administered drugs were not to be reimbursed based on AWP. *See* Plaintiffs' Opp. to Defendant Amgen, Inc.'s Individual Memo. In Support of Its Mot. to Dismiss at 5. Thus, all of the allegations relating to these drugs must be stricken. In the case of manufacturers like defendant Bristol-Myers Squibb, this eliminates most of plaintiffs' allegations. *See* Consol. Compl. at ¶¶ 379-384 (referring to alleged spreads on various physician-administered cancer drugs).

2. Generic Drugs With FULs

Federal regulations require that, where three or more versions of a generic drug exist, a Federal Upper Limit or "FUL" be set for that drug at "150% of the published price for the least costly therapeutic equivalent" -- where the "published price" is defined by "published compendia." 42 C.F.R. § 447.332. Plaintiffs contend that each generic manufacturer engaged in "FUL manipulation" by "failing to report its own lowest prices" as the "published prices." C.C. Opp. Br. at 20-21. Plaintiffs have it backwards. FULs are calculated based on the reported prices; they do not impose obligations on manufacturers about which prices to report.

A manufacturer's lowest commercial price is akin to its Medicaid "best price." Manufacturers are obligated to report confidentially to the federal government their best prices (as well as their "average manufacturer prices" or "AMPs") for Medicaid rebate purposes, but there is no corresponding obligation to report these best prices and AMPs to the publications for the purposes of Medicaid's calculating FULs. If Medicaid wanted to use Best Price and AMPs to calculate FULs, it already has that access to those prices as part of the requirements of the rebate statutes.

Indeed, if FULs were calculated based on the manufacturer's "best price," the pharmacists who pay more than 150% of that best price would be filling Medicaid prescriptions at a loss. Plaintiffs' theory is also just plain silly from an economic viewpoint. It would be commercially impractical for a manufacturer to disclose publicly the lowest or best price it gives to its most favored customer: then everyone else (competitors and other customers) would know how low the manufacturer was willing to go.

In addition, the express language of the regulations does not refer to AWP. The regulations call for setting FULs based on "published prices . . . using all available national compendia." *See* 42 C.F.R. § 447.332. The "national compendia" also publish WACs and other prices which are lower than AWPs. *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 68 (D. Mass. 2005). Plaintiffs have not even tried to allege how these other price points were allegedly "manipulated" and do not identify a single WAC as being allegedly false. Accordingly, there is no basis for plaintiffs to allege that FULs are false.

For all these reasons, plaintiffs' claims as to generic drugs with FULs should be dismissed under Fed. R. Civ. P. 9(b) and 8(a), and the Court should deny their request for leave to amend again. C.C. Opp. Br. at 21.

3. Market Prices

Plaintiffs contend that "Exhibits A and B to the Consolidated Complaint are tables that set out . . . inflated AWP, generally available market price or true AWP . . . and inflation spreads." They further argue that "[t]hese tables satisfy the Court's pleading requirement of drug by drug specificity." C.C. Opp. Br. at 19 (citing *Suffolk III* at 2). Plaintiffs, however, do not (because they apparently cannot) rebut the arguments raised by defendants in their opening brief that are fatal to these tables and thus to plaintiffs' pleadings (*See* Def. Jt. Mem. at 28):

(i) the “spread” between “inflated AWP” and alleged market prices is not pertinent because the Consolidated Complaint now alleges that WAC, not AWP, is the important benchmark (Consol. Compl. ¶¶ 7-8);

(ii) the alleged market prices in the tables are supposedly those of one wholesaler to one customer for one discrete point in time in 2000 and do not even purport to represent or particularize prices or spreads for the bulk of the time period covered by the Consolidated Complaint; and

(iii) the tables do not account for the fact that generic drugs that had FULs were reimbursed at the FULs and not the allegedly “inflated AWPs” against which the “spreads” were calculated.

In sum, a key pleading difference between this case and the class case or the cases of the Montana and Nevada Attorneys General is that the latter at least try to particularize a discrete universe of “Subject Drugs” for each manufacturer; the Counties do not. The Counties wish to complain about the WAC and best price on every NDC for which New York Medicaid reimbursed from 1992 to date, but do not want to bother doing any of the research to identify the particular facts necessary to support a viable claim. Such pleading tactics not allowed under Rules 9(b) and 8(a). Thus, any claim that survives Fed. R. Civ. P. 12(b)(6) should be dismissed under these rules.

Conclusion

For the foregoing reasons, the Court should dismiss in their entirety (1) the Consolidated Complaint (of the City of New York and all plaintiff New York Counties other than Nassau), and (2) the Second Amended Complaint of Nassau County.

Dated: Boston, Massachusetts
May 11, 2006

Respectfully Submitted,

ON BEHALF OF ALL DEFENDANTS
SERVED IN ACCORDANCE WITH FRCP. 4
OR WHO HAVE WAIVED SERVICE

By: /s/ Jacob T. Elberg
Thomas E. Dwyer (BBO No. 139660)
Jacob T. Elberg (BBO No. 657469)
DWYER & COLLORA, LLP
600 Atlantic Avenue
Boston, MA 02210
Tel: (617) 371-1000
Fax: (617) 371-1037
tdwyer@dwyercollora.com
jelberg@dwyercollora.com

Steven M. Edwards (SE 2773)
Lyndon M. Tretter (LT 4031)
Admitted *pro hac vice*
HOGAN & HARTSON LLP
875 Third Avenue
New York, NY 10022
Tel: (212) 918- 3640

Attorneys for Defendant Bristol-Myers Squibb
Company

CERTIFICATE OF SERVICE

I, Anne E. Kelly, certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on April 25, copies to Lexis-Nexis for posting and notification to all parties.

/s/ Anne E. Kelly
Anne E. Kelly